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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/767,701	01/29/2004	David K. Kovalic	38-21(53535)B	6459

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MONSANTO COMPANY
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EXAMINER	
ZHOU, SHUBO	
ART UNIT	**PAPER NUMBER**
1631	

DATE MAILED: 04/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/767,701	KOVALIC ET AL.	
	Examiner	Art Unit	
	Shubo (Joe) Zhou	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3* is/are pending in the application.

4a) Of the above claim(s) *1 and 3* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 2 is/are rejected.

7)☒ Claim(s) 2 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *See Continuation Sheet*.

Continuation of Attachment(s) 6). Other: sequence alignment between SEQ ID NO:44293 and SEQ ID NO:193538.

DETAILED ACTION

Election/Amendments

1. Applicants' election of Group II (claim 2) with traverse in the response filed 2/2/06 is acknowledged. The traversal is on the ground that examination of groups I and II together would not impose a serious search burden to the Office because nucleic acid of SEQ ID NO:12729 encodes the elected polypeptide sequence of SEQ ID NO:44293. This is not found persuasive. As set forth in the previous Office action mailed 12/2/05, the polypeptide of group II and polynucleotide of group I are patentably distinct inventions. Polypeptides, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules. While a polypeptide of group II can be made by methods using some, but not all, of the polynucleotides that fall within the scope of group I, it can also be recovered from a natural source using biochemical means. For instance, the polypeptide can be isolated using affinity chromatography. Or alternatively, the polypeptide can be made by in vitro chemical synthesis. As such, the inventions of Groups I and II have a separate status in the art as shown by their different classifications, thus the searches for the polypeptides and the polynucleotides would not coextensive. Applicants argue that coextensive search is possible when appropriate databases and search algorithms are used and that a concomitant search of the polypeptide and its polynucleotide is proper as a matter of diligence, especially if there may have been articles or papers that describe only half the story. This is not found persuasive because as the sequencing of multiple genomes are finished and due to the immense advancement of biotechnology, the number of databases of polypeptides and nucleic acids and the sizes thereof have become astronomically large, searching all the databases for both the polypeptides and

polynucleotides would almost be practically impossible and would certainly impose a serious search burden to the Office given the currently available resources in the Office. As to group III, applicants argue that search of group III would concomitantly include a search of groups I and II. This is not found persuasive because claim 3 is not dependent on claim 1 or 2 and each of three claims comprises unique limitations, e.g. claim 1 being drawn to a recombinant polynucleotide and claim 2 being drawn to a recombinant polypeptide whereas claim 3 does not contain such recombinant limitation. Further, claim 3 comprises multiple features that are not in claim 1 or 2, e.g. a polypeptide for improving cold tolerance or drought tolerance. Thus, searching of the three groups would not be coextensive, and each requires a unique search strategy.

The requirement is still deemed proper and is therefore made FINAL.

Accordingly, claims 1-3 are currently pending, and claim 2 is under consideration. Claims 1 and 3 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made with traverse in the communication filed 2/2/06.

The preliminary amendment to the specification filed 3/2/04 is acknowledged and entered.

Priority

2. It is brought to applicants' attention that for the purpose of examination, priority has not been granted to the claimed prior applications, 09/684,016, filed 10/10/2000, and 09/850,147, filed 5/8/2001, for the elected invention because the elected invention (polypeptide with the sequence of SEQ ID NO:44293) was not found to be disclosed in the claimed prior applications.

Intervening prior art may have been cited in this Office action. Applicants are requested to provide evidence that the elected invention is disclosed in the claimed applications if they wish to contest the citation of the intervening prior art.

Specification

3. The specification is objected to because of the following:

Trademarks are used in this application, such as ORACLE on page 33. Trademarks should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

The title of the invention is not descriptive. The elected invention is drawn to a recombinant polypeptide, whereas the title is directed to "Nucleic Acid Molecules and Other Molecules Associated with Plants and Uses thereof for Plant Improvement." A new title is required that is clearly indicative of the invention to which the elected claim is directed.

It is noted that the specification contains an incorporation-by-reference of the Sequence Listing and Table 1 on compact discs. See page 1. However, the creation date (January 20, 2004) listed for both the compact disc containing the sequence listing and that containing Table 1 stated in the specification is not consistent with the date (January 27, 2004) as labeled on the compact discs filed 1/29/04. It is thus not clear whether or not the contents of the compact discs filed 1/29/04 are meant to be incorporated by reference to the specification.

Appropriate correction is required.

Claim Rejections-35 USC § 101/§ 112

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claim 2 is rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility.

Claim 2 appears to be drawn to a recombinant polypeptide with a sequence of SEQ ID NO:44293. The claimed polypeptide is not supported by a specific and substantial asserted utility because none of the disclosed uses of the polypeptide as detailed on pages 10-18, etc. in the specification is specific and substantial. For example, the specification states that the claimed recombinant polypeptide is involved in one or more important biological properties in a plant. Such recombinant polypeptide may be produced in transgenic plants to provide plants having improved phenotypic properties and/or improved response to stressful environmental conditions including cold tolerance. In some cases, decreased expression of such polypeptide may be desired (see page 10). These are not specific uses for the claimed polypeptide of SEQ ID NO:44293. The specification lists a number of possible uses for the many polypeptides of SEQ ID NOS: 31565-63128 but fails to assert a specific utility for the claimed polypeptide of SEQ ID NO:44293 and none of the utilities is specifically linked to the elected polypeptide. Recently, in *In re Fisher,* a case analogous to the present application, the court held that an asserted use must also show that the claimed invention can be used to provide a well-defined and particular benefit to the public" and that "Fisher's claimed uses are nothing more than a 'laundry list' of research

plans, each general and speculative ... ." *In re Fisher*, 76 USPQ2d 1225 1229 1230 (CAFC 2005). In the instant application, applicants do not assert a particular and well-defined benefit to the public for the claimed polypeptide of SEQ ID NO: 44293.

Further, the claimed polypeptide is not supported by a substantial utility. For example, the specification states that the polypeptide can be used for improving stress tolerances, e.g. cold tolerance, in plants, etc. (page 11). However, this utility depends on the activity/function of the claimed polypeptide, and on the elucidation of the association of cold tolerance therewith, which are yet to be discovered through further research. The apparent need for such research indicates that the polypeptide is not disclosed as to a currently available or substantial utility. Similarly, the other listed and asserted utilities as summarized above or in the instant specification are neither substantial nor specific due to being generic in nature and applicable to a myriad of such compounds. Also in *In re Fisher,* the court, following an analysis of Nelson, 626 F.2d at 856 with regard to substantial utility, states that "it thus is clear that an application must show that an invention is useful to the public as disclosed in its current form, not that it may prove useful at some future date after further research." *In re Fisher*, 76 USPQ2d 1225 1230 (CAFC 2005). In the instant case, the application does not show that the claimed polypeptide is useful to the public as disclosed in its current form, but that it may prove useful at some future date after further research.

Additionally, neither the specification as filed nor any art of record discloses or suggests any property or activity for the polypeptide of SEQ ID NO:44293 such that another non-asserted utility would be well established for the polypeptide.

It is noted that the specification in Table 1 indicates that the polypeptide of SEQ ID NO:44293 shares homology with the sequence of GenBank accession number gi29150380, which appears to encode a synaptobrevin-like protein in *Oryza sativa*. One of skilled in the art, however, would have reasons to doubt that the polypeptide of SEQ ID NO:44293 would indeed be a synaptobrevin-like protein for the following reasons:

Firstly, the sequence of gi29150380 is directly submitted to GenBank and the function of the sequence is proposed based on sequence comparisons with other sequences. See the enclosed printout of GenBank accession No. AAO72389, which is also gi29150380.

Secondly, it would have been well known in the art that sequence similarity does not reliably correlate to similar or identical biological activities. For example, it would have been well known that even a single nucleotide or amino acid change or mutation is able to destroy the function of the biomolecule in many instances, albeit not in all cases. In the absence of factual evidence characterizing the structural and functional components of the biomolecule, the effects of these changes are largely unpredictable as to which ones will have a significant effect and which ones will be silent mutations having no effect. The prior art cannot *unambiguously* assign function to an unknown gene based on a homology comparison. The following example demonstrates that assignment of a metabolic gene to a known function based on homology comparisons alone provide improper functional assignment (see the homology-based methods of functional assignment of Everett et al., Nature Genetics *17*, 411-422, **1997** in light of the experimental conclusions of Scott et al., Nature Genetics *21*, 440-443, **1999**). Everett et al. disclose a homology-based functional assignment to a putative, mutated sulfate transporter gene (PDS; which encodes "pendrin") identified through positional cloning in Pendred syndrome

populations. The homology-based searches were carried out using BLAST and PSI-BLAST with commercial databases using human pendrin as the query sequence. The conclusions of Everett et al. based upon the homology comparisons were that pendrin was a transporter of sulfate. However, experimental studies by Scott et al., clearly demonstrate that pendrin, which has: 1) 29% homology to the rat sulfate-ion transporter encoded by *Sat-1*; 2) 32% homology to the human diastrophic dysplasia sulfate transporter *DTD*; and 3) 45% homology to the human sulfate transporter down-regulated in adenoma encoded by *DRA*, is not a transporter of sulfate, but of chloride and iodine instead.

Assuming *arguendo* that the polypeptide of SEQ ID NO: 44293 were indeed a synaptobrevin-like protein, one of skilled in the art would have to perform further research to determine how much its activity/function is "like" synaptobrevin, and what specific and substantial utility the protein might have. It is known that there are different members of the synaptobrevin family. For instance, Raptis et al. (Journal of Chemical Neuroanatomy, Vol. 30, pages 201-211, 2005) disclose that there are at least two isoforms of synaptobrevins, synaptobrevin/VAMP 1 and synaptobrevin/VAMP 2, which not only have different sequences, different distribution patterns, but also have different specialized roles in the neurosecretory process in animals. See Abstract and page 202, left column. Thus, it would require further research to at least determine (1) what exact function the polypeptide of SEQ ID NO:44293 would have, (2) would it be like synaptobrevin/VAMP 1 or synaptobrevin/VAMP 2, or both, and (3) how much its function would be like synaptobrevin. Once again, it is clear that the polypeptide of SEQ ID NO:44293 is not disclosed as to a currently available utility.

6. The following is a quotation of the **first** paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claim 2 is rejected under 35 U.S.C. 112, first paragraph.

Specifically, since the claimed invention lacks a patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

8. The following is a quotation of the **second** paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is written to be drawn to "a recombinant polypeptide selected from the group consisting of SEQ ID NO: 31565 through SEQ ID NO: 63128." It is not clear whether a recombinant polypeptide molecule or the sequence per se of SEQ ID NO:44293 (elected) is claimed. Note that SEQ ID NO:44293, or any of SEQ ID NO: 31565 through SEQ ID NO: 63128 for that matter, is not a polypeptide molecule per se, but rather the amino acid sequence of a polypeptide. If the polypeptide molecule is intended to be claimed, such claim amendment as " a recombinant polypeptide consisting (or comprising) the sequence of SEQ ID NO:44293" is suggested.

Clarification of the metes and bounds of the claims is requested.

Claim Rejections-35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claim 2 is rejected under 35 U.S.C. § 102(e) as being anticipated by La Rosa et al. (US 20040214272 A1, published application of 10/425,115).

In light of the indefiniteness of claim 2 as set forth above, for the purpose of this section, claim 2 is interpreted to be drawn to a polypeptide molecule consisting of the sequence of SEQ ID NO:44293.

La Rosa et al. disclose a polypeptide with a sequence that is identical to the sequence of SEQ ID NO:44293 in the instant application. The polypeptide can be produced with recombinant polynucleotide by recombinant technology and is thus a recombinant polypeptide. See the attached sequence alignment between SEQ ID NO:44293 and SEQ ID NO: 193538. Also see paragraphs 0006, 0019, 0033, 0035, 0037, and 0066.

Claim Objection

12. Claim 2 is objected to because it comprises withdrawn non-elected inventions (sequences of the SEQ ID NOS other than the elected SEQ ID NO:44293).

Conclusion

13. No claim is allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shubo (Joe) Zhou, whose telephone number is 571-272-0724. The examiner can normally be reached Monday-Friday from 8 A.M. to 4 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Patent Analyst Tina Plunkett whose phone number is (571) 272-0549.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Shubo (Joe) Zhou, Ph.D. 

Patent Examiner